ALLERGY AND ASTHMA NETWORK
MOTHERS OF ASTHMATICS, INC

Mission

To help all people affected by allergies and asthma

2751 Prosperity Ave.
Suite 150
Fairfax, VA
22031-4397
703-641-9595
800-878-4403

Fax:
703-573-7794

E-mail:
aanma@aol.com

Web site:
www.aanma.org

Leanne Cusumano
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20857
Fax: 301 827-6870; E-mail: lcusumano@cder.fda.gov

RE: Proposed rule; 21 CFR Part 2 {Docket No. 97N-0023} RIN 0910-AA99
Use of Ozone-Depleting Substances; Essential Use Determinations

November 30, 1999

Dear Ms. Cusumano,

Allergy and Asthma Network•Mothers of Asthmatics, Inc., supports the overall goals and objectives of the proposed rule. The NPR protects patient interests while ensuring continued pharmaceutical development of innovative and user-friendly non-CFC alternatives.

Furthermore, the NPR addresses the concerns expressed by families and patients in response to the ANPR in a thoughtful and thorough manner. The NPR is the type of approach patients and families expect the FDA to provide on their behalf.

As the transition moves forward AAN•MA stands prepared to assist the FDA in any manner requested. In particular, we are interested in how the transition will impact over-the-counter bronchodilator products and request specific answers as to how the FDA plans to address this issue. The NPR remains vague about treatment of OTC bronchodilators in the transition. It is difficult to comment on how this portion of the NPP would affect patients without more information from the FDA. We are prepared to meet with the FDA to provide the benefits of our research on this topic.

In addition, concerning the evaluation of policies regarding approvals of generic medications that contain CFCs, an issue which the FDA is currently examining, it is the viewpoint and experience of AAN•MA that patients will not be adversely affected in terms of out-of-pocket cost of medications or quality of life should approvals for these medications cease or continue. Generic HFA MDIs, dry powder inhalers. and nebulizer alternatives are currently in development and should continue to be encouraged rather than confuse the issue with policies that seem contrary to the purpose and intents of the transition.

Having considerable personal and professional experience with these issues, we suggest that the FDA continue to focus on the criteria that any company seeking approval of any new CFC MDIs must demonstrate clinically significant value regardless of whether the product is generic or brand name.

While the FDA wrestles with patent issues, life saving technologies, and international affairs, we trust that the overwhelming needs of patients, as measured by unbiased research and interaction with patient and medical associations, will remain the guiding force in all your decisions. As a member of the Stakeholders Group, we trust that our recommendations support your international efforts and working relationship with the EPA and other federal agencies working on our behalf.

Sincerely,

Nancy Sander
President

97N-0023

C9611